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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,764	09/27/2006	Carl Ralph Flannery	19003-002US1 AM101404	5330
26169 7590 10/15/2008 FISH & RICHARDSON P.C. P.O BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER KOSSON, ROSANNE	
			ART UNIT 1652	PAPER NUMBER
			NOTIFICATION DATE 10/15/2008	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/567,764	<b>Applicant(s)</b> FLANNERY ET AL.	
	<b>Examiner</b> Rosanne Kosson	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1, 11, 19-21 and 36-58 is/are pending in the application.
- 4a) Of the above claim(s) 36, 37, 39-41 and 43-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 11, 19-21, 38, 42 and 47-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :9/27/06, 9/7/07, 7/23 & 10/1/08.

**DETAILED ACTION*****Election/Restrictions***

Applicants' election without traverse of Groups 1 and 15, drawn to a polypeptide comprising SEQ ID NO:7 or a polypeptide comprising SEQ ID NO:9, claims 1, 11 and 19-21, in the replies filed on November 30, 2007 and February 6, 2008 is acknowledged. Applicants' elections without traverse of the species of  $\beta$ -(1-3)-Gal-GalNAc, a pharmaceutical composition that is formulated for injection, and a cytokine are also acknowledged. No claims have been amended. Claims 2-10, 12-18 and 22-35 have been canceled. Claims 36-58 have been added. Claims 36, 37, 39-41 and 43-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim. Accordingly, claims 1, 19-21, 38, 42 and 47-58 are examined on the merits herewith.

Claims 51-53 and 55-58 are drawn to non-elected inventions. But, because the polypeptide of SEQ ID NO:7 appears to be allowable over the prior art, as discussed below, these claims have been rejoined with those of the elected invention.

***Claim Rejections - 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 19-21, 38 and 42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a megakaryocyte stimulating factor (MSF), a.k.a. a proteoglycan 4 (PRG4), a.k.a. a lubricin protein, a.k.a a tribonectin, such as the polypeptide of SEQ ID NO:7, does not reasonably provide enablement for the polypeptide fragment of SEQ ID NO:9 (which is a fragment of SEQ ID NO:7). The specification discloses that SEQ ID NO:9

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encodes four or five repeats of the motif "KEPAPTT," a highly repeated motif in lubricin proteins. But, the specification does not disclose that SEQ ID NO:9 by itself has any biological or therapeutic activity. Claim 20 and its dependent claims recite a therapeutic composition comprising the polypeptide of SEQ ID NO:9. The specification discloses that the claimed polypeptides are meant to be therapeutic lubricin proteins for use in maintaining joint health or mechanical lubricants, particularly in medical devices. As a result, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether or not undue experimentation is required are summarized in *re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir.1988). The court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the breadth of the claims, (2) the nature of the invention, (3) the state of the prior art, (4) the relative skill of those in the art, (5) the predictability or unpredictability of the art, (6) the amount or direction or guidance presented, (7) the presence or absence of working examples, and (8) the quantity of experimentation necessary. Although the quantity of experimentation alone is not dispositive in a determination of whether the required experimentation is undue, this factor does play a central role. For example, a very limited quantity of experimentation may be undue

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in a fledgling art that is unpredictable where no guidance or working examples are provided in the specification and prior art, whereas the same amount of experimentation may not be undue when viewed in light of some guidance or a working example or the experimentation required is in a predictable established art. Conversely, a large quantity of experimentation would require a correspondingly greater quantum of guidance, predictability and skill in the art to overcome classification as undue experimentation. In *Wands*, the determination that undue experimentation was not required to make the claimed invention was based primarily on the nature of the art, and the probability that the required experimentation would result in successfully obtaining the claimed invention. (*Wands*, 8 USPQ2d 1406). Thus, a combination of factors which, when viewed together, would provide an artisan of ordinary skill in the art with an expectation of successfully obtaining the claimed invention with additional experimentation would preclude the classification of that experimentation as undue. A combination of *Wands* factors, which provide a very low likelihood of successfully obtaining the claimed invention with additional experimentation, however, would render the additional experimentation undue.

Factors pertinent to this discussion include the prior art, predictability of the art, guidance in the specification, the breadth of claims and the amount of experimentation that would be necessary to use the invention.

As noted above, the specification does not support the broad scope of the claims which encompasses a polypeptide comprising SEQ ID NO:9, which reads on the polypeptide of SEQ ID NO:9 alone or having as little as a single amino acid attached to either end, such as an A residue, because the specification does **not** establish that this polypeptide has any biological or therapeutic activity or that it works as mechanical lubricant.

Without sufficient guidance, beyond that provided, obtaining a composition comprising the polypeptide of SEQ ID NO:9 that works as a therapeutic composition, in particular a lubricant for

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joints, or as a mechanical lubricant is unpredictable, and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. Applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including a polypeptide comprising SEQ ID NO:9. The specification provides insufficient guidance to determine the minimum size and sequence of a polypeptide comprising SEQ ID NO:9 that is a biologically active molecule. As a result, the necessary experimentation required to determine the size and sequence of such a molecule is undue. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)).

Regarding the prior art, as cited in Applicants' IDS of September 27, 2006, Turner et al. (US 6,433,142 B1) disclose several MSF (megakaryocyte stimulating factor) proteins that comprise a region that differs from SEQ ID NO:9 by one amino acid. See SEQ ID NOS:14, 84, 74, 58, 104, 44, 42 and 142 (Results 1, 3, 5, 7, 9, 11, 13 and 15, alignments of instant SEQ ID NO:7 with the polypeptides of Turner et al., from a search in the database of sequences from issued U.S. patents, searched on December 28, 2007). The location of the sequence that differs by one amino acid from SEQ ID NO:9 is different in each of the aforementioned sequences.

In view of the foregoing, the claims fail to satisfy the enablement requirement.

***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 11, 19, 47, 48 and 52 are rejected under 35 U.S.C. 112, second paragraph, as

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being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 19 and 47 recite that the polypeptide is O-linked with  $\beta$ -(1-3)-Gal-GalNac. This claim limitation is confusing because it cannot be determined if Applicants mean that the polypeptide is O-linked to this disaccharide, as a substituent, or if the polypeptide is cross-linked with this disaccharide, e.g., the disaccharide is linked to the polypeptide at each sugar residue. As a result, the meaning of the claims is unclear. Appropriate correction is required.

Claim 52 recites that the pharmaceutical composition comprising the polypeptide of SEQ ID NO:7 further comprises a matrix. The word "matrix," as well as the placement of the matrix relative to the polypeptide are indefinite, rendering the meaning of the claims unclear. Paragraph 84 of the specification, however, discloses that the polypeptide may be placed in a conventional, implantable drug-delivery matrix. Thus, the claim may be amended to recite the composition of claim 51, wherein the composition is encapsulated in an implantable drug-delivery matrix. Appropriate correction is required.

Also, claim 11 recites an isolated protein comprising SEQ ID NO:7. "SEQ ID NO:7" is a string of letters and numbers; it is not a molecule or composition. Applicants appear to mean an isolated protein comprising the polypeptide (or the peptide or the protein) of SEQ ID NO:7. Appropriate correction is required.

#### ***Art of Record/Allowable Subject Matter***

Regarding claims 11 and 47-58, as cited in Applicants' IDS of September 27, 2006, Turner et al. (US 6,433,142 B1) disclose several MSF (megakaryocyte stimulating factor) proteins, of which SEQ ID NO:7 appears to be a splice variant. See SEQ ID NOS:2, 62, 40, 52, and 48 of Turner et al. (Results 1, 2, 10, 12 and 14, alignments of instant SEQ ID NO:7 with the

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polypeptides of Turner et al., from a search in the database of sequences from issued U.S. patents, searched on December 11, 2007). SEQ ID NO:7 lacks a polypeptide portion corresponding to amino acids 418-840 of the sequences of Turner et al. Thus, Applicants' SEQ ID NO:7 is not disclosed by the prior art.

Claims 11, 47 and 52 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action. Additionally, claim 11 must be amended to delete the non-elected subject matter, i.e., the non-elected polypeptides recited in the claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is (571)272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson  
Examiner, Art Unit 1652  
rk/2008-10-06

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/Rebecca E. Prouty/  
Primary Examiner,  
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